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10/620,221	07/15/2003	Gary A. Koppel	22064-71990	8706

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BARNES & THORNBURG LLP
11 SOUTH MERIDIAN
INDIANAPOLIS, IN 46204

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/620,221	KOPPEL, GARY A.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1,4,7-10 and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3,5-6,11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01 Dec 08 & 15 Dec 08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are presented for examination.

Applicant's Amendment filed November 21, 2008 has been received and entered into the present application.

Applicant's Information Disclosure Statements (IDS) filed December 1, 2008 (one page) and December 15, 2008 (three pages) have each been received and entered into the present application. As reflected by the attached, completed copies of form PTO-1449 (four pages total), the Examiner has considered the cited references.

Claims 1-17 remain pending. Claims 1, 4, 7-10 and 12-17 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 2-3, 5-6 and 11 remain under examination. Claim 11 is amended.

Applicant's arguments, filed November 21, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-3, 5-6 and 11 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,426,342 in view of Pfister et

al. (U.S. Patent No. 5,889,007; 1999), already of record, for the reasons of record set forth at p.7-10 of the previous Office Action dated May 21, 2008, of which said reasons are herein incorporated by reference.

Claims 2-3, 5-6 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 5-6 of U.S. Patent No. 6,610,681 in view of Pfister et al. (U.S. Patent No. 5,889,007; 1999), already of record, for the reasons of record set forth at p.10-11 of the previous Office Action dated May 21, 2008, of which said reasons are herein incorporated by reference.

Claims 2-3, 5-6 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6-7, 9-10, 14-15, 18, 27-28, 30 and 33-38 of U.S. Patent No. 6,627,625 in view of Pfister et al. (U.S. Patent No. 5,889,007; 1999), already of record, for the reasons of record set forth at p.12-14 of the previous Office Action dated May 21, 2008, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejections, stating that "the Examiner has exceeded the boundaries of a proper consultation of the specification by improperly equating a species with the term allegedly needing a definition in an attempt to bootstrap the standing obviousness-type double patenting rejection." (p.6, Remarks) Applicant argues that the '342 patent is directed to the treatment of "a condition known to result in a loss of neuronal cells or loss of neuronal cell function by reducing neuronal cell loss or function" by administering a neuroprotective compound, whereas, in contrast, the instant claims are directed to treating "cognitive disorders in human patients in need of said treatment" by administering compounds "effective to modulate neurogenic carboxypeptidase or transpeptidase activity in the brain",

and that the two conditions cannot be fairly considered obvious variants. Applicant asserts that the terms used in the '342 patent claims are "self-defining" and need no definition. Applicant admits that dementia is an example of a disorder that may "result in or from loss of neuronal cells or loss of neuronal function", but states that an example that falls within the scope of a claim term is simply not a definition of that claim term. Applicant alleges that the prior election of dementia does not change the scope of the pending claims, but "merely provides a convenient procedure for the Examiner to be used in searching the prior art." (p.8, Remarks) With regard to the rejection of the '681 patent claims and the '625 patent claims, Applicant again asserts that the Examiner has improperly relied upon the specification of the relied-upon reference and has improperly used an example species (i.e., in this case, clavulanic acid) as a "surrogate for the generic claim term" (p.9, Remarks) Applicant admits that clavulanic acid (i.e., of the instant claims) is certainly a beta-lactam compound (i.e., of the patented claims), but the collection of all beta lactam compounds is not an obvious variant of the specific beta lactam compound clavulanic acid. Applicant further argues against the application of Pfister et al., stating that the reference is completely silent to the treatment of cognitive disorders recited in the instant claims and, thus, does nothing to overcome the improper nature of the Examiner's rejection.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant is once again pointed to MPEP §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). '[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning.'); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998)." This teaching in the MPEP clearly supports the reliance upon the specification *solely to define the meaning of a term used in a patent claim*. Furthermore, since the disclosure of the cited patents clearly provides particular and specific meanings to

the terms employed in the patented claims, the reliance upon the disclosure to define such terms is clearly proper in order to fully appreciate the scope of the subject matter covered by the patented claims.

In the instant case, the disclosure of the '342 patent was relied upon to define the term "a condition known to result in a loss of neuronal cells or loss of neuronal cell function by reducing neuronal cell loss or function" as used in the patented claims, which, as evidenced by col.3, l.31-40 of the '342 patent, is specifically and particularly defined in the text of the patent as including various forms of dementia (including multi-infarct dementia, vascular dementia and neurodegenerative dementia). Such a definition, therefore, clearly supports the interpretation that the subject matter claimed in the '342 patent clearly provides for the treatment of dementia as instantly claimed using clavulanic acid as instantly claimed. Though the terms "a condition known to result in a loss of neuronal cells or loss of neuronal cell function by reducing neuronal cell loss or function" as used in the patented claims and the term "cognitive disorders in human patients in need of said treatment" may very well be, *literally speaking,* different only in language, it is clear that the meaning of each is, in fact, *not* different as evidenced by the manner in which each is defined (i.e., in the patent, such a term is defined as including various forms of dementia, and in the instant case, such a term is also defined and examined insofar as it reads upon dementia). This reliance upon the disclosure of the '342 patent is, contrary to Applicant's allegations, clearly a proper use of the disclosure to define the scope and meaning of a term used in the patented claims and to demonstrate that the subject matter of the instant claims comprises conflicting subject matter with regard to what is claimed in the '342 patent.

In fact, it appears important to point out that Applicant himself agrees that dementia is a disorder that may result in or from loss of neuronal cells or loss of neuronal function as stated in the patented claims. Please see p.7 of Applicant's remarks. However, Applicant then attempts to argue that "an example that falls within the scope of a claim term is simply not a definition of that claim term" (p.7, Remarks). This allegation is disputed. The fact that the patent defines this claim term as including

dementia in various forms is clearly a definition, *at least in part*, of the term. It may very well be (and is clearly true in the instant case, since the patent also defines this claim term as including other disorders, such as epilepsy, ALS, Alzheimer's, etc.) that there exist *other definitions to the claim terms as well*, but such a fact most certainly does not negate the definition of the term upon which the rejection relies to demonstrate that the claimed subject matter of the patent and that of the instant claims *is clearly conflicting*.

Moreover, Applicant's assertion that the prior election of dementia does not change the scope of the pending claims, but "merely provides a convenient procedure for the Examiner to be used in searching the prior art" and that the election of species is only relevant in the context of 35 U.S.C. 102 and/or 103 is not a point well taken. The purpose of the species election is for examination purposes and directs all facets of prosecution, including the evaluation of possible double patenting rejections, to focus on those species elected for examination. Applicant is reminded that he is only entitled to examination of additional species *outside of the specific species elected for examination when the generic claim is found allowable*. Please see 37 C.F.R. 1.141(a). In the instant case, the generic claims were not found to be allowable due to the rejection(s) over the elected species of disorder and compound. For this reason, the generic claim is not allowable and, thus, Applicant is not entitled to examination of additional species beyond what is elected. In other words, Applicant is correct in stating that the election of species does not literally change the scope of the claims, but is reminded that the election of species *does restrict consideration of the full scope of the claims to those specific species that Applicant has particularly elected*. Accordingly, it is maintained that that consideration of the instant claims and the patented claims insofar as they read upon the elected species of disorder (i.e., dementia) and elected species of compound (i.e., clavulanic acid) is clearly proper and in accordance with the teachings of the MPEP.

With regard to Applicant's arguments over the '681 patent, Applicant is directed to p.10-11 of the previous Office Action dated May 21, 2008 to the basis for the rejection. Nowhere in the body of the

rejection does the Examiner refer to the specification of the patent to define a term used in the claims. Accordingly, while Applicant's remarks regarding the rejection of the instant claims over the '681 patent have been fully considered, they are clearly unpersuasive because the Examiner never relied upon the patent disclosure as a dictionary to define a term used in the patented claims. As a result, Applicant's remarks to such effect are clearly moot.

Still further, Applicant additionally argues also against the rejection set forth over the patented claims of the '625 patent, stating that (1) the Examiner improperly relied upon the specification, (2) has improperly used an example species to define the generic claim term and (3) though admitting that clavulanic acid is certainly a beta-lactam compound, alleges that the collection of all beta-lactam compounds is not an obvious variant of the specific beta-lactam compound clavulanic acid. This, again, as before, is unpersuasive. The Examiner again relies upon the teaching in MPEP §804, which clearly supports the reliance upon the patent specification to define a term used in the claims. In the instant case, the disclosure of the '625 patent was relied upon to define the term "a beta-lactam compound" as used in the patented claims, which, as evidenced by col.10, l.13-30 of the '342 patent, is specifically and particularly defined in the text of the patent as including clavulanic acid. Such a definition, therefore, clearly supports the interpretation that the subject matter claimed in the '625 patent clearly provides for the treatment of a patient suffering from senile dementia as instantly claimed using clavulanic acid as instantly claimed.

Once again, it appears important to point out that Applicant himself agrees that clavulanic acid is a beta-lactam compound as stated in the patented claims. Please see p.9 of Applicant's remarks. However, Applicant's argument that the collection of all beta-lactam compound is not an obvious variant of the specific beta-lactam compound clavulanic acid is unpersuasive. The fact that the patent defines this claim term "beta-lactam compound" as including clavulanic acid is clearly a definition, *at least in part*, of the term. It may very well be (and is clearly true in the instant case, since the patent also defines this

claim term as including other beta-lactams, such as penicillins, cephalosporins, penems, azetidinones, etc.) that there exist *other definitions to the claim terms as well*, but such a fact most certainly does not negate the definition of the term upon which the rejection relies to demonstrate that the claimed subject matter of the patent and that of the instant claims *is clearly conflicting*.

Lastly, in response to Applicant's arguments that the reference to Pfister et al. is completely silent as to the treatment of cognitive disorders recited in the instant claims and, thus, does nothing to overcome the improper nature of the rejection, Applicant is reminded that Pfister et al. was *not relied upon* for a teaching of the elected P-glycoprotein efflux inhibitor for the same purpose of treating cognitive disorders, but rather was relied upon for its teaching that the elected P-glycoprotein efflux inhibitor increases permeation of active agents through the blood-brain barrier and, thus, acts as a chemosensitizing agent. As a result, one of skill in the art at the time of the invention would have been motivated to use such an efflux pump inhibitor in combination with clavulanic acid to enhance the bioavailability of the active agent by increasing permeation of the agent through the blood-brain barrier. The fact that Pfister et al. does not specifically teach the treatment of cognitive disorders is not relevant to the basis of the rejection as it was previously set forth because such an argument fails to address the motivation set forth and relied upon to make the asserted combination. Moreover, the rejection was set forth as relying upon a *combination of references*, not a single reference alone. As a result, focusing solely on the discrete teachings of each of the cited references is tantamount to examining each of them inside of a vacuum and fails to be persuasive because it is the *combined* teachings that are the basis of the rejection, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately.

For the reasons presented *supra*, and those previously made of record at p.7-14 of the Office Action dated May 21, 2008, rejection of claims 2-3, 5-6 and 11 remains proper.

Conclusion

Rejection of claims 2-3, 5-6 and 11 is proper.

Claims 1, 4, 7-10 and 12-17 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Leslie A. Royds/
Patent Examiner, Art Unit 1614

January 28, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614